

REMARKS

Pursuant to the entry of the instant amendment, claims 1-29 are presently pending. Applicant respectfully submits that, of these, claims 9-11, 15, 18-21, and 26-29 read on the elected invention of Group II, directed to a method of treating skin conditions with a semi-solid composition formulated for topical administration comprising a polyunsaturated fatty acid fraction extracted from *Nigella sativa* L. seeds and a pharmaceutical carrier. Accordingly, only claims 1-8, 16, 17, and 22-25 should be withdrawn from consideration.

Claims 9, 15, 18, and 21 are amended herewith. Regarding the amendments to the claims presented herein:

Claim 9 has been amended to more clearly specify the types of skin conditions to be treated or prevented through the topical administration of an effective amount of the semi-solid composition of the instant claims. In particular, claim 9 now specifies that the skin condition arises from “fungal infection, bacterial infection, allergic reaction, or inflammation”. Specific examples of such conditions are set forth in pending claim 11. Applicant presents this amendment purely for the purposes of expediting prosecution. As such, it should not be interpreted as Applicant’s agreement with the Examiner’s position.

Explicit support for the amendment to claim 9 is found in the specification as originally filed, for example:

- at p. 2, line 28 to p. 3, line 3 (“In a further embodiment, the present invention provides novel uses for the *Nigella sativa* L. polyunsaturated fatty acid fraction including methods for treating and preventing anal fissures and hemorrhoids, methods for treating or preventing skin conditions, methods for treating or preventing inflammation, pain of allergic reactions, methods for treating or preventing bacterial and fungal infections and/or modulating fungal and bacterial growth, by topically administering an effective amount of a composition comprising the *Nigella sativa* L. polyunsaturated fatty acid fraction.”);
- at p. 6, lines 17-18 (“The present invention also provides novel methods for treating and preventing fungal infections...”);

- at p. 8, lines 6-7 (“The present invention also provides novel methods for treating and preventing bacterial infections...);
- at p. 9, lines 14-16 (The present invention provides methods for treating or preventing inflammation, pain, and/or allergic reactions . . .”);
- at p. 9, lines 9-11 (“With respect to dry skin, the compounds and compositions of the present invention produce eicosanoids. These important hormone-like compounds dampen inflammatory reactions in the skin.”); and
- p. 11, lines 1-2 (“The present invention provides methods for treating and preventing septic wounds or infected septic wounds. . .”).

In addition, the objective studies described in the examples conclusively demonstrating anti-fungal, anti-bacterial, anti-inflammatory, and anti-allergic properties of the *Nigella sativa* L. polyunsaturated fatty acid fraction provide inherent support for a method of treating and preventing skin conditions arising from such circumstances. Thus, Applicant submits that no new matter has been added.

Claims 15 and 18-21 are amended herewith to depend directly or indirectly from independent claim 9 so as to render them readable on the instantly elected invention. Accordingly, Applicant requests consideration of the merits of these claims.

Applicant respectfully submits that the instant response renders moot the outstanding claim rejections and places the instant application in condition for allowance. Further to this position, Applicant submits the following remarks:

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 9-11 and 26-29 stand rejected 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement because, while the specification is enabling for the treatment of certain skin conditions, such a fungal and/or bacterial infections, it does not reasonably provide enablement for the prevention of all skin conditions. According to the Examiner, the term “prevention” is an absolute term which implies complete cessation. Given that “no known disease can be absolutely prevented at this time” and the fact that “the prevention

of all skin conditions would entail different mechanisms of action”, the Examiner concludes that the scope of the instantly claimed invention exceeds the scope of enablement.

Applicant respectfully disagrees with the Examiner’s characterization of the term “prevent”. The instant specification at p. 8, lines 19-24, defines “treating and preventing” skin conditions as including “eliminating or curing the condition, reducing the size or severity of the condition (e.g., compared to the size or severity of the condition before the compounds or compositions of the present invention were administered), and/or reducing the rate of progression of the condition growth of the fungal infection (e.g., compared to the rate of growth in the absence of the compounds or compositions of the present invention).” In addition, www.wikipedia.org defines “prevention” in the medical context as any activity which “reduces the burden of mortality or morbidity from disease”. Prevention can occur “at primary, secondary and tertiary prevention levels.” While “primary prevention avoids the development of a disease, secondary and tertiary levels of prevention encompass activities aimed at preventing the progression of a disease and the emergence of symptoms as well as reducing the negative impact of an already established disease by restoring function and reducing disease-related complications.

Accordingly, Applicant respectfully submits that, contrary to the Examiner’s suggestion, the term “prevent”, when afforded its ordinary and customary meaning, does not necessarily equate to absolute cessation. Moreover, Applicant respectfully submits that one skilled in the art would readily recognize that, in the context of the instant claims, prevention encompasses a wide range of prophylactic therapies aimed at alleviating the severity of a multitude of undesired skin conditions, ranging from bacterial and fungal infections to those associated with allergic and/or inflammatory reactions, such as psoriasis, eczema, dermatitis, and the like. Thus, Applicant respectfully submits that claims 9 *et seq.* are commensurate with the admitted scope of enablement. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claims 9-11 and 26-29 under 35 U.S.C. § 112, first paragraph in view of the amendments and remarks herein.

Claims 9-11 and 26-29 stand further rejected 35 U.S.C. § 112, first paragraph for failing to comply with the enablement requirement because, while the specification is enabling for the treatment of certain skin conditions, such a fungal and/or bacterial infections, it does not reasonably provide enablement for the treatment of all skin conditions. According to the Examiner, the term “skin condition” reads on a divergent group of diseases, ranging from skin cancer and Kaposi sarcoma to diaper rash, “yet the specification does not enable the prevention of skin cancer, Kaposi sarcoma,” and the like. Reiterating that “the predictability of preventing a skin conditions is relatively low given that various known skin conditions are characterized by different etiologies”, the Examiner asserts that “to one skilled in the art, prevention of a skin condition is highly unpredictable”. The Examiner thus concludes that “applicant is enabled for a method of treating fungal or bacterial skin conditions (i.e., diaper rash) but not for the treatment of any skin condition.”

The test of enablement is whether one reasonably skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation. For an Examiner to sustain a rejection on the grounds of enablement, he or she must provide evidence that the claimed method could not be performed without undue experimentation. In this case, Applicant submits that the Examiner’s “evidence” does not support her conclusion. Specifically, while the entirety of the Examiner’s concerns relates to the unpredictability of “prevention” (discussed in greater detail above), her conclusion of lack of enablement extends to “treatment” as well. In that a specification is presumed to be in compliance with the enablement requirement of 112, first paragraph, the burden is on the Patent Office to establish a reasonable basis to question enablement. In this case, as the Examiner has presented no evidence supporting the unpredictability or lack of guidance vis-à-vis treatment of skin conditions, Applicant respectfully submits that she has failed to meet her burden under the statute. Nevertheless, solely in an effort to expedite prosecution, Applicant has amended claim 9 to specify the particular skin conditions contemplated. In particular, claim 9 as amended specifies that the skin condition arises from “fungal infection, bacterial infection, allergic reaction or inflammation”. Enabling support for such applications is found in the specification as originally filed, such support not only including general direction and guidance but also working examples confirming the asserted utilities. See in particular Examples 7, 9, 10, 11, 13 and 16,

which conclusively demonstrate the anti-fungal, anti-bacterial, anti-inflammatory, and anti-allergic effects of the *Nigella sativa* L. polyunsaturated fatty acid fraction. Thus, in that the treatment of such conditions is amply supported by the instant specification, Applicant respectfully submits that the claims so amended are commensurate with the scope of enablement. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claims 9-11 and 26-29 under 35 U.S.C. § 112, first paragraph in view of the amendments and remarks herein.

Rejections under 35 U.S.C. § 103

Ahmad in view of Berg:

Claims 9-11 and 26 stand rejected under 35 U.S.C. § 103(a) for being obvious over Ahmad et al. (US 2005/0058735) in view of Berg (Advances in Dermatology, 1988).

According to the Examiner, Ahmad teaches a method of treating skin diseases using a composition derived from *Nigella sativa* L. seeds in an amount no less than 20% w/v, more particularly a pharmaceutical composition formulated as a hydrogel lotion or cream for topical delivery. However, the Examiner admits that Ahmad fails to specifically teach a method of treating a skin condition, such as diaper rash, with a specific range of polyunsaturated fatty acids free of saturated fatty acids and glyceryl esters. To cure this deficiency, the Examiner cites to Berg, noting that Berg teaches that common diaper dermatitis entails a group skin disorders and therefore would qualify as a skin disease disclosed by Ahmad. The Examiner thus concludes that, in view of the Berg disclosure, the treatment of a skin condition such a diaper rash with the semi-solid *Nigella sativa* L. formulation disclosed by Ahmad would have been obvious to one of ordinary skill in the art

Applicant respectfully disagrees with the Examiner's characterization of the prior art as well as her conclusion of obviousness. Contrary to the Examiner's suggestion, Ahmad does not teach "a method of treating skin diseases using compositions derived from extract of *Nigella sativa* L seeds in an amount no less than 20% w/v". Rather, Ahmad merely mentions in passing that "many members of the family Ranunculaceae can be used for treatment of a variety of conditions, including *skin diseases*, hemorrhoids, cancer, endothelial cell progression, decrease in the production of the angiogenic protein-fibroblastic growth factor made by tumor cells and

inhibition of the growth factor made for endothelial cells.” (paragraph [0019], emphasis added). The fact that “many members” of the family Ranunculaceae have certain known applications does not serve as a teaching that one specific botanical composition (i.e., a polyunsaturated fatty acid fraction extracted from *Nigella sativa*) is suitable for use in the treatment of one of the specifically mentioned disorders (i.e., skin conditions such as diaper rash). In that the remainder of the Ahmad disclosure is directed to novel applications for compositions extracted from members of the Family: Ranunculaceae, Subclass: Dicotyledonae or Crassinucelli, Superorder: Ranunculales in the treatment of liver and immunological disorders, more particularly hepatitis, Applicant respectfully submits that Ahmad fails to disclose or suggest a method of treating or preventing any skin condition with a *Nigella sativa* extract. Furthermore, while the Ahmad compositions are generally described as suitable for “oral, parenteral, topical, and nasal delivery as well as by suppository, contemplating solid dosage-forms, liquids, suspensions, intramuscular, subcutaneous, intravenous, and transdermal delivery systems”, the examples and preferred embodiments all relate to the treatment of hepatitis C with an intramuscular injection preparation. Given these limitations, Applicant respectfully submits that one of ordinary skill in the art would not have been motivated to combine the teachings of Ahmad et al. with those of Berg et al. to provide a semi-solid composition formulated for topical administration comprising a polyunsaturated fatty acid fraction extracted from *Nigella sativa* L. seeds and a pharmaceutically acceptable carrier.

On a further note, Applicant respectfully submits that the Examiner’s suggestion that the invention is “obvious” in view of the prior art is in conflict with her prior characterization of the treatment and prevention of skin conditions as “unduly unpredictable” (wherein she notes that various known skin conditions are characterized by “different etiologies” and “different mechanisms of action”). In contrast, in discussing the obviousness rejection, she suggests that it would merely be a matter of routine to utilize the Ahmad compositions in the treatment of any skin condition, including diaper rash, despite the fact that the entirety of the reference relates to the treatment of liver and immunological disorder, particularly hepatitis C (HCV). If the treatment of skin disorders is indeed as unpredictable as the Examiner suggests, one of ordinary skill in the art clearly could not have reasonably expected the suggested modification to be

operable. In that obviousness requires at least a reasonable expectation of success, Applicant submits that for this additional reason, the instant obviousness rejection is flawed.

Thus, in that the cited references, alone or in combination, fail to suggest the invention of the pending claims, Applicant respectfully submits that allegation of obviousness rejection is in error. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claims 9-11 and 26 under 35 U.S.C. § 103(a) in view of the amendments and remarks herein.

Ahmad in view of Berg & Nickavar:

Claims 28-29 stand rejected under 35 U.S.C. § 103(a) for being obvious over Ahmad et al. (US 2005/0058735) in view of Berg (Advances in Dermatology, 1988) and Nickavar (Naturforsch, 2003).

According to the Examiner, Nickavar cures the deficiencies of Ahmad and Berg by disclosing a chemical composition of the fixed oil of *Nigella sativa* L. comprising 23.4% oleic acid and 55.6% linoleic acid. The Examiner submits that the Nickavar reference demonstrates that the quantity of *Nigella sativa* L extract utilized by Ahmad provides a composition that falls within the claimed range (i.e., a polyunsaturated fatty acid fraction no less than 16.5%).

Applicant respectfully disagrees and submits that the Nickavar reference fails to cure the above-noted deficiencies of Ahmad and Berg. In particular, Nickavar fails to provide a motivating suggestion to formulate the Ahmad extract as a semi-solid composition suitable for topical administration and to utilize such in a method of treating or preventing skin conditions “arising from fungal infection, bacterial infection, allergic reaction, or inflammation” as required by the claims as amended herewith.

Thus, in that the cited references, alone or in combination, fail to suggest the invention of the pending claims, Applicant respectfully submits that the conclusion of obviousness is in error. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claims 28-29 under 35 U.S.C. § 103(a) in view of the amendments and remarks herein.

Ahmad in view of Berg, Schlenk, and Ali:

Claim 27 stands rejected under 35 U.S.C. § 103(a) for being obvious over Ahmad et al. (US 2005/0058735) in view of Berg (Advances in Dermatology, 1988), Schlenk et al. (JACS, 1950), and Ali et al. (PTR, 2002).

Applicant respectfully disagrees and submits that the Schlenk and Ali references fail to cure the above-noted deficiencies of Ahmad and Berg. In particular, neither Schlenk nor Ali provides a motivating suggestion to formulate the Ahmad extract as a semi-solid composition suitable for topical administration and to utilize such in a method of treating or preventing skin conditions “arising from fungal infection, bacterial infection, allergic reaction, or inflammation” as required by the claims as amended herewith.

Thus, in that the cited references, alone or in combination, fail to suggest the invention of the pending claims, Applicant respectfully submits that the conclusion of obviousness is in error. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection of claim 27 under 35 U.S.C. § 103(a) in view of the amendments and remarks herein.

CONCLUSION

The outstanding Office Action set a three-month shortened statutory period for response. Pursuant to the entry of Applicant’s petition for a one month extension of time, response is due on or before **January 13, 2008**. Accordingly, Applicant submits that this response is timely and that no additional fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to the undersigned’s Deposit Account No. **50-2101**.